The Reuse of Single-Use Devices

FDA Proposed Strategy: Concept in Development

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Beginning of Practice

- **Reuse of reusable devices started in 1960s**
- **Advent of single use devices (SUDs) early 1980s: Determination of label from the Original Equipment Manufacturer (OEM)**
- **Economics is driving force for reprocessing**
- **In the US, most reprocessing done by hospitals**
- **Growth in third party reprocessing companies**

FDA's Position Historically

- **Reprocessing in hospitals/clinics (Compliance Policy Guide 300.500)**
- **Any person engaged in single use device reprocessing is a "manufacturer"**
- **Premarket submissions have not been requested**

FDA's Position Historically
(continued)

- **Requirements of 3rd Party Reprocessing Firms:**
  - **Device Registration and Listing, 21 CFR, Part 807**
  - **Good Manufacturing Practice (GMP) Inspection, 21 CFR, Part 820**
  - **Medical Device Reporting, 21 CFR, Part 803**
  - **General Labeling Requirements, 21 CFR, Part 801**
- **Reuse Policy Documents & Correspondence on FDA Web Page (www.fda.gov/cdrh/reuse)**

Simple Solutions?

- One voice in the debate suggests calling for identical regulatory controls for reprocessing as for OEMs - call for 510(k)s and PMAs
- An opposing voice suggests we leave General Controls in place as sufficient: Registration and Listing, GMP (Quality System Requirements), Labeling, and Medical Device Reporting
- Neither approach is satisfactory

Problems to Solve

- Minimal evidence of public health problems does not mean that the current practice is safe and effective
- This system inside hospitals and in third parties has grown over time with FDA tacit acceptance
- Reuse is basically a problem of economics and ethics: both are outside of FDA mandate!

Some Guiding Principles

- Capitalize on what we do best: understanding of regulatory control and devices
- Our constraints suggest the importance of partnering/outside leveraging: show leadership but do not solve all by ourselves
- Do not let the perfect serve as the enemy of the good

Regulatory Strategy by Risk

- Develop a risk categorization scheme
- Use this to determine the timing of submitting premarket notification
- Determine how to judge safety and effectiveness of SUD reprocessing
- Work with hospitals and others to educate widely concerning FDA requirements
- Develop enforcement strategy
- Promote research to obtain better data base

Risk Categorization Scheme

- **Establishes a way to evaluate the level of risk associated with the reuse of a SUD**
- **Assumes that reprocessing or reuse adds to the inherent risk of the SUD**
- **Begins with the inherent risk associated with the classification of a device into Class I, II, or III**
- **Evaluates the additional risk that may result from reuse**

Critical Premarket Issues

- **How to establish device specifications to ensure device is (as) safe and effective**
- **How to detect changes to devices by OEM and the need for revalidation**
- **Ability to perform thorough process definition and validation studies given facility and sterilizer limitations**

Enforcement Issues

- **Timeframe for submitting data, including registration and listing, depends on what data agency will require**
- **Huge education and terminology problem**
  - **Hospitals and physician's offices have little experience with FDA**
- **FDA should have one set of requirements for OEMs, 3rd party reprocessors, hospitals, physician offices**

The Potential Role of Standards

- Three dozen existing standards may apply: mostly in cleaning, sterilizing
- Some new horizontal standards needed
- Issues that need to be covered include verification of sterility after reprocessing
- New product specific vertical standards will be needed, but
  - these will take time and considerable cooperation from clinical community

The Role of Research

- Continued wide support for more research
- Research needed to develop meaningful endpoints such as residuals
- Research needed on the performance endpoints for device specific standards
- Need to develop worst case scenario to narrow amount of testing

Vision for the Future

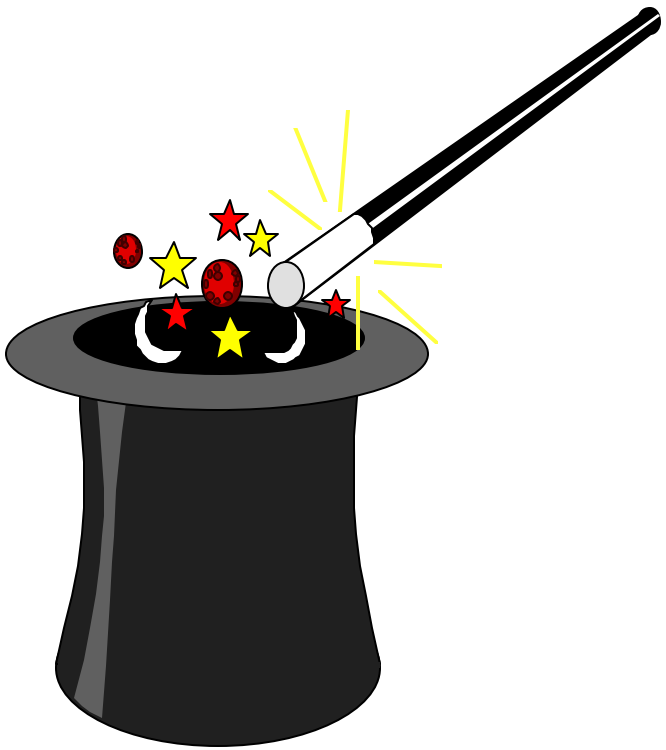
Current Reality

- Widespread practice with little data on safety or effectiveness
- Single use labels not clearly meaningful
- Single use labels don't identify vulnerabilities
- Patients are not informed - experimentation?

Future Vision

- FDA regulatory approach will be RISK and SCIENCE based
- Single use labels will have clinical relevance
- Single use labels will identify vulnerabilities
- Horizontal and vertical standards critical
- Leverage outside parties

Time for Action and a Bit of Magic!



- **FDA now taking all comments into consideration**
- **FDA will begin to issue guidance early in 2000 and changes to the reuse of SUDs will happen soon after**
- **Magic? How to do this with clearly inadequate resources!**
- **Although consensus has not been achieved, we are much closer; we will get there!**